Food Canning Establishment Registration, Process Filing and Recordkeeping for Acidified Foods and Thermally Processed Low-Acid Foods in Hermetically Sealed Containers

0910-0037

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

Under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), FDA is authorized to prevent the interstate distribution of food products that may be injurious to health or that are otherwise adulterated, as defined in section 402 of the FD&C Act (21 U.S.C. 342). Under the authority granted to FDA by section 404 of the FD&C Act (21 U.S.C. 344), FDA regulations require registration of food processing establishments, filing of process or other data, and maintenance of processing and production records for acidified foods and thermally processed low-acid foods in hermetically sealed containers. These requirements are intended to ensure safe manufacturing, processing, and packing procedures and to permit FDA to verify that these procedures are being followed. Improperly processed low-acid foods present life-threatening hazards if contaminated with foodborne microorganisms, especially *Clostridium botulinum*. The spores of *C. botulinum* must be destroyed or inhibited to avoid production of the deadly toxin that causes botulism. This is accomplished with good manufacturing procedures, which must include the use of adequate heat processes or other means of preservation.

In the *Federal Register* of March 14, 2007 (72 FR 11990), FDA published a proposed rule entitled "Temperature-Indicating Devices; Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers" (the proposed rule). This document proposed to revise FDA's regulations for thermally processed low-acid foods in part 113 to, among other things, provide for the use of temperature-indicating devices other than mercury-in-glass thermometers during processing, require that temperature-indicating devices be tested for accuracy against a calibrated reference device, and to establish recordkeeping requirements for temperature-indicating devices and reference devices maintained by the processor. In compliance with the PRA (44 U.S.C. 3506(c)(2)(B)), the Agency requested public comment on the information collection provisions of the proposed rule (72 FR 11990 at 12004).

On March 3, 2011 (76 FR 11892), FDA published a final rule entitled "Temperature-Indicating Devices; Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers" (the final rule). The final rule revises the information collection currently approved under OMB control number 0910-0037 by adding recordkeeping requirements in new § 113.100(c) and (d). The information to be recorded under these regulations is related to accuracy tests of temperature-indicating devices and reference devices maintained by processors of low-acid canned foods. These tests must be performed to ensure the accuracy of the devices during the processing of these foods. If these devices are not accurate, the processor cannot ensure that the low-acid canned foods it produces are safe to eat, and consumers may be harmed. The recordkeeping requirements of the final rule are necessary to document that appropriate accuracy tests have been performed with the appropriate frequencies for each temperature-indicating device and each reference device maintained by the processor. Records of accuracy tests for these devices also help processors

determine how frequently the devices should be tested for accuracy. Much of the information is currently generated for accuracy tests performed under current regulations. However, the information may not be recorded as required under the final rule.

Current low-acid canned food regulations recommend, but do not require, that processors keep records of accuracy tests for mercury-in-glass thermometers, including test date, standard used, method used, and person performing the test. The final rule requires processors to keep records documenting the accuracy of temperature-indicating devices (including but not limited to mercury-in-glass thermometers) and of reference devices that are maintained by the processor. These records include the identifier of the device being tested, such as its tag or seal; the name of the manufacturer of the device; the identity of the reference device, equipment, and procedures used for the accuracy test and to adjust the device or, if an outside facility conducts the accuracy test, documentation regarding the traceability of the accuracy to a National Institute of Standards and Technology or other national metrology institute standard; the identity of the person or facility that performed the accuracy test and adjusted or calibrated the device; the date and results of each accuracy test, including the amount of adjustment; and the date on or before which the next accuracy test must be performed.

In addition to requesting public comment on the new recordkeeping provisions, the proposed rule also stated that FDA had submitted the recordkeeping provisions to OMB for review (72 FR 11990 at 12005). However, due to an administrative error, the Agency did not actually do so, and, therefore, FDA is submitting them to OMB now.

We request OMB approval of the paper and/or electronic versions of Forms FDA 2541, FDA 2541a, and FDA 2541c and the reporting and recordkeeping burdens contained in the following citations:

21 CFR 108.25(c)(1) - Reporting (Establishment Registration)

Commercial processors file information on each establishment engaged in processing acidified foods not later than 10 days from start-up.

21 CFR 108.25(c)(2) - Reporting (Process Filing)

Provide information on the scheduled processes before packing any new acidified food product not later than 60 days after registration.

21 CFR 108.25(d) - Reporting

Requires packers to report any instance of potential health endangering significance wherein the food has entered distribution in interstate commerce.

21 CFR 108.25 (e) - Recordkeeping

Requires processors of acidified foods to develop and keep on file plans for recalling products that may endanger the public health.

21 CFR 108.25(g) - Recordkeeping

Requires packers to prepare, review, and retain all production records for 3 years from date of manufacture.

21 CFR 108.35(c)(1) - Reporting (Establishment registration)

Commercial processors file information on each establishment engaged in processing low-acid foods not later than 10 days from start-up.

21 CFR 108.35(c)(2) - Reporting (Process Filing)

Provide information on the scheduled processes for low-acid foods prior to packing any new product.

21 CFR 108.35(c)(2)(ii) - Reporting (Process Filing)

Intentionally modified process shall be substantiated as to its adequacy and recorded in writing in the packer's files prior to its use and to report process changes to FDA within 30 days after first use.

21 CFR 108.35(c)(2)(ii) - Recordkeeping

Requires packer to record and file full information on any change of a previously filed scheduled process.

21 CFR 108.35(d) - Reporting

Requires packers to report any instance of spoilage or process deviation the nature of which indicates potential health significance wherein the food has entered distribution.

21 CFR 108.35(e) - Reporting

Requires packer to report any instance wherein such food, which may be injurious to health because of microbial contamination, has entered distribution.

21 CFR 108.35(f) - Recordkeeping

Requires processors of thermally processed low-acid foods sealed in hermetically sealed containers develop and keep on file plans for recalling products that may endanger the public health.

21 CFR 108.35(h) - Recordkeeping

Requires a commercial processor to prepare, review, and retain all records of processing, processing deviations, container closure inspections, and other records for a period of 3 years.

21 CFR 113.60(c)- Recordkeeping

Requires thermally processed low-acid foods in hermetically sealed containers be marked with an identifying code to permit lots to be traced after distribution.

21 CFR 113.83 - Recordkeeping

Requires preparation and permanent retention of complete records covering process establishment by the person or organization establishing the process.

21 CFR 113.87(a) - Recordkeeping

Requires that process data must be filed prior to packing any new product, and operating processes and procedures must be posted near the processing equipment or made available to the operator.

21 CFR 113.89 - Recordkeeping

Requires a record of evaluation procedures used for process deviation evaluations for thermally processed low-acid foods; a separate file or log identifying process deviations, and the actions taken.

21 CFR 113.100 - Recordkeeping

Specifies processing and production information to be observed and recorded by retort or processing operator.

21 CFR 114.80(b) – Recordkeeping

Requires acidified foods be marked with an identifying code to permit lots to be traced after distribution.

21 CFR 114.89 - Recordkeeping

Retention of records of procedures and results of evaluating acidified finished food products for potential hazard to public health.

21 CFR 114.100(a) through (d) - Recordkeeping

Specifies three year retention of records and reports dealing with production processes and controls.

2. Purpose and Use of the Information Collection

To protect the public health, FDA regulations require that each firm that manufactures, processes, or packs acidified foods or thermally processed low-acid foods in hermetically sealed containers for introduction into interstate commerce register the establishment with FDA using Form FDA 2541 (§§ 108.25(c)(1) and 108.35(c)(1) (21 CFR 108.25(c)(1) and 108.35(c)(1))). In addition to registering the plant, each firm is required to provide data on the processes used to produce these foods, using Form FDA 2541a for all methods except aseptic processing, or Form FDA 2541c for

aseptic processing of low-acid foods in hermetically sealed containers (§§ 108.25(c)(2) and 108.35(c)(2)). Plant registration and process filing may be accomplished simultaneously. Process data must be filed prior to packing any new product (§§ 108.25(c)(2) and 108.35(c)(2)). For processors of thermally processed low-acid foods in hermetically sealed containers, operating processes and procedures must be posted near the processing equipment or made available to the operator (§ 113.87(a) (21 CFR 113.87(a))).

Regulations in parts 108, 113, and 114 (21 CFR parts 108, 113, and 114) require firms to maintain records showing adherence to the substantive requirements of the regulations. These records must be made available to FDA on request. Firms are also required to document corrective actions when process controls and procedures do not fall within specified limits (§§ 113.89, 114.89, and 114.100(c)); to report any instance of potential health-endangering spoilage, process deviation, or contamination with microorganisms where any lot of the food has entered distribution in commerce (§ 108.25(d) and § 108.35(d) and (e)); and to develop and keep on file plans for recalling products that may endanger the public health (§§ 108.25(e) and 108.35(f)). To permit lots to be traced after distribution, acidified foods and thermally processed low-acid foods in hermetically sealed containers must be marked with an identifying code (§§ 113.60(c) (thermally processed foods) and 114.80(b) (acidified foods)).

The records of processing information are periodically reviewed during factory inspections by FDA field investigators and Center personnel to verify fulfillment of the requirements in 21 CFR 113 or 114. Scheduled thermal processes are examined and reviewed to determine their adequacy to protect public health. In the event of a public health emergency, records are used to pinpoint potentially hazardous foods rapidly and thus limit recall activity to affected lots.

Description of Respondents: The respondents to this information collection are commercial processors and packers of acidified foods and thermally processed low-acid foods in hermetically sealed containers. Respondents are from the private sector (for-profit businesses).

3. Use of Improved Information Technology and Burden Reduction

FDA permits electronic registration of food canning establishments (FCE) on the Internet via the FCE online registration system. The agency estimates that about eighty percent (80%) of the registrations will be submitted electronically in the next three years. FDA permits electronic process filing on the Internet via the Low Acid Canned Food (LACF) Program entitled *eLACF*. Food canning establishments can request an electronic account by sending an email to lacf@fda.hhs.gov. The agency estimates that about eighty percent (80%) of the process filings will be submitted electronically in the next three years. Both applications are available through the FDA Unified Registration and Listing System (FURLs).

4. Efforts to Identify Duplication and Use of Similar Information

To the best of our knowledge, no other federal government agency is engaged in the collection of this information. There can be no duplicative collection of this information because the information maintained in fulfilling the statutory requirements under section 404 of the FD&C Act is unique to each establishment.

5. Impact on Small Businesses or Other Small Entities

FDA estimates that ten percent (10 %) of respondents are small businesses. The information collected is of a regulatory nature and the requirements are the same for small or large food processing establishments. FDA aids small businesses in complying with its requirements through the agency's Regional Small Business Representatives and through the administrative and scientific staffs within the agency. FDA has provided a Small Business Guide on the agency's website at http://www.fda.gov/oc/industry/.

6. Consequences of Collecting the Information Less Frequently

Data collection occurs occasionally. The information cannot be collected less frequently. Commercial processors engaging in the manufacture, processing, or packing of acidified foods or thermally processed low-acid foods in hermetically sealed containers are required to register with FDA on Form FDA 2541 within 10 days of so engaging, and to file scheduled processes on Forms FDA 2541a, or 2541c, within 60 days of registration and prior to the packing of a new product. This timing for reporting assures against improperly or inadequately processed or packed acidified foods or thermally processed low-acid foods in hermetically sealed containers being introduced into interstate commerce and becoming a public health threat to the nation.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

The collection fully complies with 5 CFR 1320.5(d)(2). There are no special circumstances associated with this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In the *Federal Register* of March 14, 2007 (72 FR 11990), FDA published a proposed rule entitled "Temperature-Indicating Devices; Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers" (the proposed rule). In compliance with the PRA (44 U.S.C. 3506(c)(2)(B)), the Agency requested public comment on the information collection provisions of the proposed rule (72 FR 11990 at 12004). FDA received six letters, each containing one or more comments on the proposed rule. Although the Agency did not identify any comments referring specifically to the PRA, several comments discussed the proposed recordkeeping provisions. FDA has summarized and responded to these comments in section II of the final rule (Comments 1, 4, 11 through 13, and 18).

(Comment 1) One comment requested that the effective date of this final rule be not less than 1 year from the date of publication. The comment indicated that companies that are continuing to use mercury-in-glass thermometers will need time to comply with the additional recordkeeping requirements for accuracy checks. Furthermore, companies with existing water retorts will need at least 1 year to comply with the additional equipment requirements of the regulation. The comment also indicated that firms that currently reprocess products or rework previously processed product into a new formulation need at least 1 year tore view existing process schedules and conduct confirmatory testing if necessary, to comply with § 113.83 (21CFR 113.83).

(Response) We agree with the comment's request to allow 1 year for processors to comply with recordkeeping requirements relating to use of mercury-in-glass thermometers and to other

requirements relating to temperature-indicating devices established in this final rule. Thus, the effective date of this final rule is 1 year from the date of publication in the Federal Register. However, FDA does not agree with the comment's suggestion that processors need a year to comply with § 113.83 for reprocessed or reworked product. As discussed in our response to comment 38, although we clarified the requirements in final§ 113.83, we did not propose new requirements for reprocessed or reworked products in the proposed rule or establish new requirements for reprocessed or reworked products in this final rule.

(Comment 4) One comment recommended revising proposed§ 113.40(a)(1) to require temperature-indicating devices to be tested for accuracy against a reference device for which the accuracy is traceable to a National Institute of Standards and Technology (NIST), or equivalent, standard reference device.(Response) We agree with the comment. We revised the applicable proposed requirements to clarify that each temperature-indicating device and each reference device that is maintained by the processor must be tested for accuracy against a reference device for which the accuracy is traceable to a NIST, or other national metrology institute, standard reference device(final § 113.40(a)(1), (b)(1), (c)(1), (d)(1),(e)(1), (f)(1), and (g)(1)(i)(A)). The term "reference device maintained by the processor" refers to the reference device used by a processor who performs the accuracy tests at the processor's own facility or facility laboratory. For such reference device, the processor, rather than a third party laboratory, irresponsible for ensuring accuracy of the reference device when it is used for the accuracy test and for ensuring that its accuracy is traceable to a NIST, or other national metrology institute, standard reference device. The term "traceable" refers to "metrological traceability," which is defined in the International Vocabulary of Metrology as the "property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty" (Ref. 2). "Measurement result" is defined as a "set of quantity values being attributed to a measurand together with any other available relevant information" (Ref. 3) and "measurement uncertainty" is defined as "the non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used" (Ref. 4). This final rule also clarifies that the record of the accuracy test for a temperature-indicating device or a reference device maintained by the processor must include documentation of the traceability of the accuracy of the reference device to a NIST, or other national metrology institute, standard reference device (final § 113.100(c) and(d) (21 CFR 113.100(c) and (d))). For an accuracy test performed by the processor and, thus, for which the processor maintains the reference device, the documentation of traceability must be a guarantee, certificate of accuracy, certificate of calibration, or other document from the manufacturer or other source of the reference device. For an accuracy test performed by an outside facility, the documentation of traceability must be a guarantee, certificate of accuracy, certificate of calibration, or other document from the facility that includes a statement or other documentation regarding the traceability of the accuracy to a NIST, or other national metrology institute, standard reference device. The information required to be included in the records of accuracy for temperature-indicating devices and reference devices was set forth in proposed § 113.40(a)(1)(ii), (b)(1)(ii),(c)(1)(ii), (d)(1)(ii), (e)(1)(ii), (f)(1)(ii),and (g)(1)(i)(A)(2). To eliminate redundancy, we moved the information requirements for the records of accuracy for temperature-indicating devices and reference devices maintained by the processor from each of these sections to final § 113.100(c) and (d) of Subpart F—Records and Reports. We redesignated proposed § 113.100(c), (d), and (e), as final § 113.100(e), (f), and (g), respectively. We also revised proposed § 113.87(c) (21 CFR 113.87(c)) to clarify that the records of accuracy tests for temperature-indicating devices used to determine the initial product temperature and reference devices maintained by the processor must be maintained in accordance with§ 113.100(c) and (d).

(Comment 11) One comment expressed concern about the information required in proposed§ 113.40(a)(1)(ii)(A) and (a)(1)(ii)(B) for documentation of accuracy of temperature-indicating devices and reference devices. The comment suggested that the final rule should instead require documentation that conforms to the standards established by the American National Standards Institute, National Conference of Standards Laboratories (ANSI/NCSL) or the International Organization for Standardization, International Electrotechnical Commission (ISO/IEC) for accrediting calibration laboratories. The comment stated that the laboratory accreditation standards indicate acceptable reporting practices. The comment acknowledged that the standards may be too prescriptive for food processors who perform their own calibrations.

(Response) We do not agree that the regulation should require the documentation of accuracy of temperature-indicating devices and reference devices to conform to the standards specified in the comment for accrediting calibration laboratories. Although FDA supports use of accredited calibration laboratories and recognizes that the laboratories must maintain certain documentation for the accreditation, the records required by this final rule are appropriately limited to those necessary to document that the temperature-indicating device was tested for accuracy at sufficient frequency to ensure accuracy during processing. As acknowledged by the comment, a requirement for processors to adhere to accreditation standards would impose an unnecessary burden on those who successfully perform their own calibrations but are not accredited by ANSI/NCSL or ISO/IEC.
(Comment 12) One comment recommended revising proposed§ 113.40(a)(1)(ii)(A) and (a)(1)(ii)(B) to require that documentation of the results of the accuracy test include before and after data, i.e., the temperature reading of the temperature-indicating device compared to the accurate calibrated reference device, before and after the calibration. The comment indicated that the before data is needed because it is the basis for determining whether the device was accurate at the time of calibration and for documenting any adjustment that was made.

(Response) Proposed§ 113.40(a)(1)(ii)(A) and (a)(1)(ii)(B) require that the results of each accuracy test be documented. Although not explicitly stated in the proposed rule, we would expect documentation of the results of the accuracy test to include information about the amount of calibration adjustment that was necessary. The “before and after data” suggested by the comment would be reflected in the amount of calibration adjustment. The amount of calibration adjustment is an indication of whether the temperature-indicating device was accurate at the time of the calibration. If an adjustment is required, the processor should evaluate the need for more frequent accuracy tests and also determine whether food processed prior to the adjustment is under processed. To provide clarity in the regulation regarding the requirement to record the amount of calibration adjustment that was necessary for a temperature-indicating device, we are revising final § 113.100 “Processing and production records” to indicate that the record of each accuracy test for each temperature-indicating device and for each reference device that is maintained by the processor must include the results of each accuracy test, including the amount of calibration adjustment (final§ 113.100(c)(5) and (d)(5)). Other information relating to the results of the accuracy test that should be recorded when it is relevant includes information about the condition of the temperature-indicating device (i.e., intact or broken mercury column, worn or broken components) and disposition of the temperature-indicating device if it cannot be calibrated (i.e., destroyed, repaired, or replaced).

(Comment 13) One comment addressed the proposed requirement that records of the accuracy test for the temperature-indicating device include the date of the next scheduled accuracy test (proposed

§ 113.40(a)(1)(ii)(A),(b)(1)(ii)(A), (c)(1)(ii)(A), (d)(1)(ii)(A), (e)(1)(ii)(A), (f)(1)(ii)(A), and(g)(1)(i)(A)(2)(i)). One comment interpreted this requirement to imply that the test must be conducted on that specific date. The comment suggested removing the requirement or changing the language to "the date of the calibration expiration."

(Response) We acknowledge that the proposed requirement concerning the date of the next scheduled accuracy test may be misinterpreted to mean that the next accuracy test must be conducted on that specific date. However, we do not agree that the revised language recommended by the comment, i.e., the date of the calibration expiration, adequately clarifies that the next accuracy test must be conducted on or before the specified date. In this final rule, we require that the record of accuracy for a temperature-indicating device and a reference device maintained by the processor include the date on or before which the next accuracy test must be performed (final§ 113.100(c)(6) and (d)(6)).

(Comment 18) One comment objected to the requirement for "written documentation," found in proposed §§ 113.40(a)(1)(ii), (b)(1)(ii), (c)(1)(ii),(d)(1)(ii), (e)(1)(ii), (f)(1)(ii), and(g)(1)(i)(A)(2). The comment indicated that the term "written" implies handwritten documentation and will limit new documentation technologies. The comment stated that the term "written" should be removed to allow for means of documentation other than just written records, especially since the Agency proposed in § 113.100(f) to allow electronic records. The comment also stated that the term "written" should be removed from other sections of the regulations that apply to records.

(Response) We do not agree that the term "written" implies that the documents are hand-written. Written documentation may be generated mechanically, such as when a stylus generates a tracing onto a paper chart, or electronically, including computer generated documents. However, we do agree that the term is not necessary for describing the requirements for establishing and maintaining records. Therefore, in this final rule, we used the term "record" or "records" without the qualifying term "written" (final §§ 113.87(e) and 113.100(b) and (e)). For consistency, we also removed the qualifying term "written" from§ 113.87(b). In addition, where the term "written documentation" is intended to mean "records" that must be established and maintained, we changed the term "written documentation" to "records" (final § 113.40(a)(1)(ii), (b)(1)(ii),(c)(1)(ii), (d)(1)(ii), (e)(1)(ii), (f)(1)(ii),and (g)(1)(i)(A)(2)).

9. Explanation of Any Payment or Gift to Respondents

FDA does not provide any payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

All production records and inspection reports collected from establishments by FDA during inspections are maintained in FDA District Compliance files which have limited access. The food processing information contained on Forms FDA 2541a and FDA 2541c is privileged and confidential. The process filing information is safeguarded in locked files at the Center for Food Safety and Applied Nutrition, FDA, and are accessible only to properly authorized FDA and contractor personnel. Any records that the agency may copy or take possession of would be protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)), and by part 20 of the agency's regulations (21 CFR part 20). The

information also is safeguarded by Section 301(j) of the act (21 U.S.C. 331(j)).

11. Justification for Sensitive Questions

This information collection does not involve questions that are of a personally sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

Description of Respondents: The respondents to this information collection are commercial processors and packers of acidified foods and thermally processed low-acid foods in hermetically sealed containers.

The total annual estimated burden imposed by this collection of information is 2,380,467 hours annually (4,852 + 2,375,615 = 2,380,467).

12 a. Annualized Hour Burden Estimate

FDA estimates the burden of this information collection as follows:

Table 1.--Estimated Annual Reporting Burden[1]

Form No.	21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Form FDA 2541 (Registration)	108.25 and 108.35	515	1	515	.17 (10 minutes)	88
Form FDA 2541a (Process Filing)	108.25 and 108.35	1,489	8.62	12,835	.333 (20 minutes)	4,274
Form FDA 2541c (Process Filing)	108.35	84	7.77	653	.75 (45 minutes)	490
Total						4,852

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA bases its estimates of the number of respondents and the hours per response on its experience with registration and process filing and on information from industry. FDA estimates the total burden of registration under §§ 108.25 and 108.35 to be 88 hours (515 respondents x 1 annual response x 0.17 hours = 87.55 hours, rounded to 88 hours). FDA estimates the total burden of process filing on Form FDA 2541a under §§ 108.25 and 108.35 to be 4,274 hours (1,489 respondents x 8.62 annual responses x 0.333 hours = 4,274.12 hours, rounded to 4,274 hours). FDA estimates the total burden of process filing on Form FDA 2541c under § 108.35 to be 490 hours (84 respondents x 7.77 annual responses x 0.75 hours = 489.51 hours, rounded to 490 hours). The reporting burden for § 108.25(d) and § 108.35(d) and (e) is minimal because notification of spoilage, process deviation, or contamination of product in distribution occurs less than once per year. Most firms discover these problems before the product is distributed and, therefore, are not required to report the occurrence. To avoid double-counting, estimates for §§ 108.25(g) and 108.35(h) have not been included because they merely cross-reference recordkeeping requirements contained in parts 113 and 114.

Table 2.--Estimated Annual Recordkeeping Burden[1]

21 CFR Part/Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
21 CFR Parts 113 and 114	9,500	1	9,500	250	2,375,000
Burden added by new § 113.100(c) and (d)	4,225	15	63,375	0.0097 (35 seconds)	615
Total					2,375,615

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA received six letters, each containing one or more comments on the proposed rule. Although the Agency did not identify any comments referring specifically to the PRA, several comments discussed the proposed recordkeeping provisions. FDA has summarized and responded to these comments in section II of the final rule (Comments 1, 4, 11 through 13, and 18). None of the comments on the proposed rule suggested that we modify our burden estimates for the new information collection provisions. Thus, we have not changed our estimates of the annual frequency per recordkeeping or the hours per record. We have, however, increased the estimated number of recordkeepers to reflect growth in the low-acid canned food processing industry since the 2007 proposed rule.

Currently, there are 9,491 active firms in the LACF database, which encompasses processors of low-acid canned food, processors of acidified food, and processors of both types of food. Thus, we estimate the number of processors keeping records under parts 113 and 114 to be 9,500, as shown in table 2, row 1 of this document. In the final rule, we estimated that there are approximately 8,450 foreign and domestic low-acid canned food processing establishments. This estimate, which does not encompass establishments that process only acidified foods (because such processors are not affected by the final rule), was based on data in the LACF database as of September 2009. As discussed in the explanation of the recordkeeping estimate for the final rule in the following paragraphs, our estimate assumes that half of the LACF industry currently does not record all of the device accuracy testing information that the final rule requires. Thus, as shown in table 2, row 2 of this document, we estimate that 4,225 low-acid canned food manufacturers that are not currently keeping the records that are required under the final rule will begin to keep such records to comply with the final rule when it becomes effective.

FDA bases its estimates of the number of recordkeepers and the hours per record on its experience and on information from industry. FDA estimates that it takes 250 hours per respondent to comply with the recordkeeping requirements in parts 113 and 114. In table 2, row 1 of this document, FDA estimates the total burden of recordkeeping under parts 113 and 114 before the effective date of the final rule to be 2,375,000 hours (9,500 respondents x 250 hours = 2,375,000 hours). Table 2, row 2 reports the average annual recordkeeping burden of the final rule. The burden of the recordkeeping requirement of the final rule consists of the set-up time required to design and establish a form for recording the required information, and the additional hours of labor needed to record the information. The set-up time required for designing a new recordkeeping form is assumed to be minimal because we estimate that only a few data elements required in the final rule are currently

unreported by some processors and that only small modifications to a processor's recordkeeping form would be required to accommodate the additional data elements.

We estimate that the amount of time needed to comply with the recordkeeping requirements of the final rule will be small because current industry practice is to keep track of most, if not all, of this information. Because current incentives to track accuracy of mercury-in-glass thermometers may vary across the industry, however, some information that is currently generated during accuracy tests may not be recorded as required under the final rule. Thus, we assume there will be a burden incurred from the final rule to record information that is currently generated, but not recorded.

We assume that half of the industry currently does not record all of the device accuracy testing information that the final rule requires. We further assume that current practice by these firms is to leave unrecorded 1 to 4 separate pieces of information required under the final rule, and that each piece of information takes between 10 and 15 seconds to record. Consequently, we estimate that half of all low-acid canned food manufacturers will spend between 10 seconds and 1 minute (i.e., 1 x 10 seconds and 4 x 15 seconds) per device to record information required in the final rule.

Based on a survey conducted by FDA between 1992 and 1993 of mercury-in-glass thermometer calibration in the low-acid canned food industry, we estimate that low-acid food firms use an average of 10 temperature-indicating devices, including reference devices. We estimate that 4,225 low-acid canned food manufacturers (half of the industry) currently do not fully record the accuracy test results required by the final rule. Because the regulations specify that each device must be tested upon installation and at least once per year thereafter, or more frequently if necessary to ensure accuracy, we estimate that each device requires 1 to 2 tests per year (midpoint of 1.5 tests per year). We therefore estimate the annual frequency per recordkeeping to be 15 (i.e., 10 devices x 1.5 tests per year). We estimate the burden for recording the additional information to be between 10 and 60 seconds per device (midpoint of 35 seconds or 0.0097 hours per device). Therefore, the estimated total annual burden in hours for the recordkeeping requirements of the final rule is approximately 615 hours (63,375 x 0.0097 = 614.7 hours, rounded to 615 hours). Thus, the final rule increases the total burden of this information collection by approximately 0.3 percent, from 2,375,000 hours to 2,375,615 hours.

12 b. Annualized Cost Burden Estimate

The annual hour cost burden to respondents is approximately $142,494,755 per year. FDA estimates that the average hourly wage for the employee preparing and submitting the registrations and process filings would be equivalent to a GS-11/Step-1 level in the locality pay area of Washington-Baltimore in 2011, approximately $29.93/hour. Doubling this wage to account for overhead costs, FDA estimates the average hourly cost to respondents to be $59.86/hour. Thus, the overall estimated cost incurred by the respondents is $142,494,755 (2,380,467 burden hours x $71.76/hr = $142,494,755).

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating, or maintenance costs associated with this collection.

14. Annualized Cost to the Federal Government

The annualized costs to the Federal government are $895,820. Approximately 2.5 person years (PY) are expended by food technologists for technical review of the process filing forms (FDA 2541a and 2541c). In addition, approximately 1.5 PY are expended for administration, coordination and computer programming. A contractor provides new system development, computer data entry and administrative support (filing, mail handling) for the project. The cost of the contract is $230,000 per year. The estimated annual cost of printing forms and instructions is $1,000.00.

The annual burden for on-site review of the manufacturers records is approximately 2 hours at $71.26 an hour, or $142.52, for each on-site records inspection. On average, a total of 400 inspections are performed each year for a total cost of $57,008. The burden for the review of records which have been copied and forwarded to CFSAN because of potential problems is approximately 6 hours at $71.26 an hour, or $427.56 per event. On average, records for 35 inspections each year are reviewed by CFSAN for a total cost of $14,964. Thus, the total cost for FDA inspection and review is $71,972.

One person year (PY) for a fully supported FDA employee equals 2080 hours at a cost of $148,212. The estimated costs incurred by the Government are listed below:

o Contract (annual expense)	$230,000
o Food Technologists - 1.5 PY	$222,318
o Technicians - 2.5 PY	$370,530
o Printing	$ 1,000
o On-site Inspections	$ 57,008
o Records Inspections	$ 14,964
Total	$895,820

15. Explanation for Program Changes or Adjustments

This is a revision request in which the burden hours for the final rule “Temperature-Indicating Devices; Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers” are being added to the information collection currently approved under OMB control number 0910-0037. We estimate that the recordkeeping requirements in new § 113.100(c) and (d) add 615 hours. Due to the rulemaking, we are characterizing this revision as a program change due to agency discretion.

In addition, parts 113 and 144 reflect an adjustment increase in the total burden hours from 1,863,500 hours to 2,375,000, an increase of 511,500 hours. This increase is due to a large increase in the estimated number of recordkeepers, as compared with three years ago. Thus, the total increase in the estimated recordkeeping burden as a result of the revision and adjustment is 512,115 hours (615 + 511,500 = 512,115).

Finally, although FCEs may now register online, we have not changed the average burden per response in Table 1, Row 1, because we expect that 0.17 hour (10 minutes) is still an accurate

reflection of the time that it takes to fill in the data elements, whether the respondent is using the FCE online registration (given that the system is new to registrants) or filling in a fillable pdf, printing and mailing it. When this collection is next revised or extended, we will have better data with which to analyze the comparative average burden per response.

16. Plans for Tabulation and Publication and Project Time Schedule

The information obtained from this data collection will not be published.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

There are no reasons why display of the expiration date for OMB approval of the information collection would be inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.